

## **REMARKS**

### **Status of the Claims**

Claims 1 and 4-10 are pending in the above-identified application. Claim 8 is amended herein to delete the phrase "without stirring." Thus, no new matter has been added.

Applicants respectfully request the withdrawal of the finality of the Office Action for the reasons discussed below. Should the Examiner not grant such request, Applicants submit that the present Amendment is merely formal in nature, reduces the number of issues under consideration, and places the case in condition for allowance. Alternatively, entry of the present amendment is proper to place the claims in better form for appeal.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

### **Request for Withdrawal of Finality of Office Action**

On November 30, 2009, Applicants' Representative contacted the Examiner to inquire about the above-identified application. At that time, the Examiner indicated that she would **not** give a first Office Action made final if Applicants added new claims 9-11. These claims were added in the Amendment filed December 1, 2009.

Since these claims were new, the Examiner has not treated these claims on the merits. Thus, finally rejecting claims 9-10 in the Office Action mailed June 22, 2010 was improper and necessitates that the finality of the Office Action mailed June 22, 2010 be withdrawn.

Applicants submit that the Examiner's new rejection is the first time these rejections of claims 9-10 have been made by the Examiner. Not until the final rejection was issued could Applicants ascertain which references and statutes were being applied to reject claims 9-10.

Accordingly, withdrawal of the finality of the outstanding Office Action is respectfully requested.

### **Examiner's Interview**

Applicants would like to thank the Examiner for her time during the interview on August 5, 2010. Applicants appreciate the courtesies extended to them in this application. Based on the discussions during the interview, Applicants believe that the claims are now in condition for allowance. Should the Examiner believe that there remains any outstanding issues, Applicants

respectfully request that the Examiner contact Applicants' Representative so as to expedite resolution of these outstanding issues, via an Examiner's Amendment or the like.

### **Drawings**

Since no objection has been received, Applicants assume that the drawings are acceptable and that no further action is necessary. Confirmation thereof is respectfully requested.

### **Issues under 35 U.S.C. § 112, first paragraph**

Claims 8-10 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner asserts that the phrase "without stirring" is not supported by the present specification.

Although Applicants respectfully traverse the Examiner's assertion, claim 8 has been amended herein by deleting the phrase "without stirring." As such, Applicants respectfully request that this rejection be withdrawn.

### **Issues under 35 U.S.C. § 103(a)**

1) Claims 1, 4, 6, and 8-9 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Josephson et al. '029 (US 2003/0092029) in view of Rohr '970 (US 5,445,970) and further in view of Thompson '304 (US 2003/0190304).

2) Claims 5, 7, and 10 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Josephson et al. '029 in view of Rohr '970 and Thompson '304 and further in view of Foster '879 (US 4,444,879).

Applicants respectfully traverse. Reconsideration and withdrawal of these rejections are respectfully requested based on the following considerations.

Legal Standard for Determining Prima Facie Obviousness

MPEP 2141 sets forth the guidelines in determining obviousness. First, the Examiner has to take into account the factual inquiries set forth in *Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), which has provided the controlling framework for an obviousness analysis. The four *Graham* factors are:

- (a) determining the scope and content of the prior art;
- (b) ascertaining the differences between the prior art and the claims in issue;
- (c) resolving the level of ordinary skill in the pertinent art; and
- (d) evaluating any evidence of secondary considerations.

*Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966).

Second, the Examiner has to provide some rationale for determining obviousness. MPEP 2143 sets forth some rationales that were established in the recent decision of *KSR International Co. v Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

As the MPEP directs, all claim limitations must be considered in view of the cited prior art in order to establish a *prima facie* case of obviousness. See MPEP 2143.03.

Distinctions over the Cited References

Independent claims 1 and 8 recite that “the spacer is polyalkylene glycol having 50 to 500 repeat units.” The present specification states:

While spacers of various lengths may be used in the present invention, spacers have a specific length of preferably 10 Å to 2000 Å, more preferably 200 Å to 2000 Å in order to produce a higher effect. Such a length can be obtained by, for example, in the case of polyalkylene glycol (hereinafter may be abbreviated as PALG), a structure in which 2 to 500, particularly 50 to 500, PALG monomers are repeated. When polyethylene glycol (hereinafter PEG) is used as polyalkylene glycol, the length can be obtained when polyethylene glycol has a weight average molecular weight of 2200 to 22000, preferably approximately 3000 within 2500 to 4000 (paragraph [0015]).

In other words, the weight average molecular weight of the polyalkylene glycol is related to its length.

In this regard, Example 3 of the present specification provides an example using a PEG-attached secondary antibody 1 compared with a PEG-attached secondary antibody 2 wherein the PEG has a lower molecular weight. As shown in Tables 3-4 (reproduced below), the PEG-attached secondary antibody 1 provides unexpectedly superior results over PEG-attached secondary antibody 2. As the Examiner admits, Josephson et al. '029 do not disclose a "polyalkylene glycol having 50 to 500 repeat units." Thus, PEG-attached secondary antibody 2 strongly evidences that the cited references do not produce the results of the present invention since the criticality of a "polyalkylene glycol having 50 to 500 repeat units" has been proven.

[Table 3]

Beads used	Conditions of labeling of secondary antibody with magnetic beads	Purified antigen concentration antigen: ribosomal protein L7/L12 of Mycoplasma pneumoniae			
		100 ng/ml	10 ng/ml	1 ng/ml	Negative sample
Dynabeads MyOne Streptavidin	Magnetic bead-labeled, PEG-attached secondary antibody 1	O	O	O	×
	Magnetic bead-labeled, PEG-attached secondary antibody 2	O	O	×	×
	Magnetic bead labeled secondary antibody 3 (no PEG)	O	O	×	×

In the table, "O" means that magnetic beads were observed in the CCD camera observation.

"×" means that magnetic beads were not observed in the CCD camera observation.

[Table 4]

Beads used	Conditions of labeling of secondary antibody with magnetic beads	Purified antigen concentration antigen: ribosomal protein L7/L12 of Mycoplasma pneumoniae			
		100 ng/ml	10 ng/ml	1 ng/ml	Negative sample
Dynabeads MyOne Streptavidin	Magnetic bead-labeled, PEG-attached secondary antibody 1	601 mV	83 mV	52 mV	below detection limit
	Magnetic bead-labeled, PEG-attached secondary antibody 2	337 mV	55 mV	below detection limit	below detection limit
	Magnetic bead labeled secondary antibody 3 (no PEG)	462 mV	57 mV	below detection limit	below detection limit

Relevant to these § 103(a) rejections, *Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966) has provided the controlling framework for an obviousness analysis, wherein a proper analysis under § 103(a) requires consideration of the four *Graham* factors. One such factor includes the evaluation of any evidence of secondary considerations (e.g., commercial success; unexpected results). 383 U.S. at 17, 148 USPQ at 467. In this regard, Applicants respectfully submit that the present invention has achieved unexpected results, whereby such results rebut any asserted *prima facie* case of obviousness. See *In re Corkill*, 711 F.2d 1496, 226 USPQ 1005 (Fed. Cir. 1985). Also, the comparative showing need not compare the claimed invention with all of the cited prior art, but only with the closest prior art. See MPEP 716.02(b) and 716.02(e).

According to MPEP 2145, rebuttal evidence and arguments can be presented in the specification, *In re Soni*, 54 F.3d 746, 750, 34 USPQ2d 1684, 1687 (Fed. Cir. 1995). Office personnel should consider all rebuttal arguments and evidence presented by Applicants. See, e.g., *Soni*, 54 F.3d at 750, 34 USPQ2d at 1687 (error not to consider evidence presented in the specification). Rebuttal evidence may also include evidence that the claimed invention yields unexpectedly improved properties or properties not present in the prior art. Rebuttal evidence may consist of a showing that the claimed compound possesses unexpected properties. *In re Dillon*, 919 F.2d 688, 692-93, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990).

As stated in *KSR International Co. v Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007), “rejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” Furthermore, the mere fact that references *can* be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art. *Id.* As described above, Applicants have shown that the present invention achieves unexpected and unpredictable results. Thus, due to the unexpected results as achieved by the present invention, the rejections have been overcome. Reconsideration and withdrawal of these rejections are respectfully requested. Any contentions of the USPTO to the contrary must be reconsidered at present.

**Conclusion**

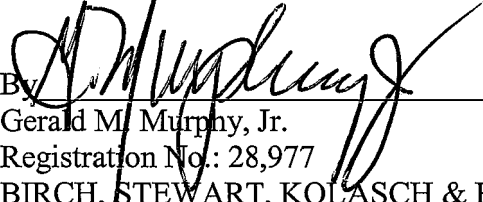
All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Chad M. Rink, Registration No. 58,258, at the telephone number of the undersigned below to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Director is hereby authorized in this, concurrent, and future replies to charge any fees required during the pendency of the above-identified application or credit any overpayment to Deposit Account No. 02-2448.

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Respectfully submitted,

  
By \_\_\_\_\_  
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